A Plus Medical
Solutions for Respiratory Care

510(k) Summary

K092687

Owner:

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Owner/Operator Number:

10023166

NOV 2 8 2009

Official Contact:

Thomas C. Loescher
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Trade Names:

Venti.Plus™ Hyperinflation Bag System with Pressure Manometer

Common/Usual Name:

Hyperinflation Bag with Pressure Manometer

Classification Name:

Device Name:	Resuscitator, Manual, Non Self-Inflating
Product Code:	NHK
Regulation:	CFR 868.5905
Device Class:	II
Device Name:	Monitor, Airway Pressure
Product Code:	CAP
Regulation:	CFR 868.2600
Device Class:	II

Device:

Venti*Plus Hyperinflation Bag System with Pressure Manometer

Predicate Devices:

Number:	K970785
Product Name:	SIMS Hyperinflation Bag System
Manufacturer:	Smiths Medical (Intertech Resources)
Product Codes:	008330DM, 008330VM, 008332DM, 008335DM, 008430, 008430DM, 00843M, 008430T,, 008430VM, 008431T, 008432, 008432DM, 008432T, 008435 & 008435DM
Number:	K961318
Product Name:	1st Response Disposable Manometer
Manufacturer:	Smiths Medical (Intertech Resources)
Product Codes:	008201

Device Description:

Single patient use hyperinflation bag with pressure manometer offered in 0.25, 0.50 and 1.0 liter ventilation bag sizes. End user manipulates gas flow and respiratory rate and exhalation port to control amount of gas, inspiratory and expiratory pressure supplied to the patient. Each device has an integrated 0 – 60 cm H_2O pressure manometer.

Indications for Use:

Single patient use non self-inflating manual resuscitator for use in hospital and transport to temporary ventilate neonate, infant and pediatric patients. The pressure manometer in this product provides a visual indication of airway pressure during ventilation.

Contraindications:

None identified.

Patient Population:

Patient populations of neonate, newborn and pediatric.

Environment of Use:

Hospital and patient transport

Comparative of Technological Characteristics:

The A Plus Medical Venti*Plus Hyperinflation System with Pressure Manometer is substantially equivalent in indications for use, environment of use, patient population, material and function to the identified predicate. The A Plus Medical Venti*Plus Hyperinflation System with Pressure Manometer and identified predicate device meet the requirements set forth ISO 5356- 1:2004 entitled "*Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets*". Bench testing confirmed that the A Plus Medical Venti*Plus Hyperinflation System with Pressure Manometer and predicate device have similar performance characteristics and the accuracy of the integrated pressure manometer in the Venti*Plus Hyperinflation System with Pressure Manometer is equivalent to the predicate device when used with its associated pressure manometer.

Conclusion:

The Venti*Plus Hyperinflation System with Pressure Manometer is substantially equivalent to the identified predicates.
The Venti*Plus Hyperinflation System with Pressure Manometer and the identified predicates have substantially equivalent performance.
The Venti*Plus Hyperinflation System with Pressure Manometer and the identified predicates are made from substantially equivalent material, intended use, patient populations and environment of use

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room W-O66-0609
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President
A Plus Medical
5431 Avenida Encinas, Suite G
Carlsbad, California 92008-4411

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Re: K092687
Trade/Device Name: Venti.Plus™ Hyperinflation Bag System with Pressure Manometer
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: NHK
Dated: November 4, 2009
Received: November 10, 2009

Dear Mr. Loescher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A Plus Medical
Solutions for Respiratory Care

Indications for Use Statement

510(k) Number: K092687 (To be assigned)

Device Name: Venta.Plus™ Hyperinflation Bag System with Pressure Manometer

Indications for Use:

Single patient use non self-inflating manual resuscitator for use in hospital and transport to temporary ventilate neonate, infant and pediatric patients. The pressure manometer in this product provides a visual indication of airway pressure during ventilation.

Prescription Use X **or** **Over-the-counter use** __
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092687